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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,150	06/24/2003	Robin Callan	100070.401C1	3537

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EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
12/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/606,150	CALLAN ET AL.	
	Examiner	Art Unit	
	JENNIFER MYONG M. KIM	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *September 2, 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5,6 and 8-74* is/are pending in the application.

4a) Of the above claim(s) *16-56* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5,6,8-15 and 57-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/3/2008;2/15/2008; 9/2/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The response filed September 2, 2008 have been received and entered into the application.

Action Summary

The rejection of claims 1, 3, 5, 6, 8-15 and 57-74 under 35 U.S.C. 112, first paragraph is being maintained for the reasons stated in the previous Office Action.

Response to Arguments

Applicants' arguments filed September 2, 2008 have been fully considered but they are not persuasive. Applicants argue that not all of the rejected claims require the presence of water and/or a therapeutically effective amount of iron because claims 61-67 are specifically directed to a "dry" dialysate precursor composition which does not comprising water or a therapeutically effective amount of iron. This is not found to be persuasive because the claims 61-67 drawn to "comprising" does not exclude water or iron and that claim 68 depend from claim 61 further defines what is the element comprised by claim 61. Applicants argue that the specification pages 20-21 disclose which forms of iron are considered to be compatible. This is not found to be persuasive because the disclosures in the specification has been carefully reviewed and considered. It refers the term "iron" as both ferric and ferrous form of iron as well as

complexes of iron particularly iron dextran and that "ferric" form such as "ferric gluconate", another iron complex that requires a great deal of time and skill for administration. However, the "Ash" (WO 98/06482A1) reference teaches that iron dextran causes severe allergic reactions, fever and rashes during injection and that only about half of iron in the iron dextran is bioavailable. Therefore, it is highly speculative that any type of iron would work as a precursor dialysate to serve as a dialysate composition without undue experimentation. Therefore, a dialysate precursor composition comprising citrate at a concentration raging from about 20 to about 900mEq/L; a buffering anion selected from acetate and/or lactate; water; chloride at a concentration ranging from about 1,000 to about 7,000 mEq/L; at least one physiologically-acceptable cation; and a therapeutically effective amount of **iron** is not considered to be enabled by the instant specification. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 3, 5, 6, 8-15 and 57-74 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a "dialysate precursor composition comprising citrate at a concentration raging from about 20 to about

900mEq/L; a buffering anion selected from acetate and/or lactate; water; chloride at a concentration ranging from about 1,000 to about 7,000 mEq/L; at least one physiologically-acceptable cation; and a therapeutically effective amount of **specific form of iron**", does not reasonably provide enablement " a dialysate precursor composition comprising citrate at a concentration raging from about 20 to about 900mEq/L; a buffering anion selected from acetate and/or lactate; water; chloride at a concentration ranging from about 1,000 to about 7,000 mEq/L; at least one physiologically-acceptable cation; and a therapeutically effective amount of **iron**." The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

3. Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, state of the prior art and the amount of experimentation necessary. All of the **Wands factors** have been considered with regard to the instant claims, with the most relevant factors discussed below.

> ***Nature of the Invention***: All of the rejected claims are drawn to a dialysate precursor composition comprising citrate at a concentration raging from about 20 to about 900mEq/L; a buffering anion selected from acetate and/or lactate; water; chloride at a concentration ranging from about 1,000 to about 7,000 mEq/L; at

least one physiologically-acceptable cation; and a therapeutically effective amount of **iron**. The nature of the invention is extremely complex in that it encompasses the actual dialysate precursor composition such that the composition comprising iron.

Breath of the Claims: The complex of nature of the claims greatly exacerbated by breath of the claims. The claims encompass **any types of iron** in the dialysate precursor composition. Each of which may or may not be addressed by the administration of the claimed composition.

Guidance of the Specification: The guidance given by the specification as to how one would administered the claimed composition with iron to formulate a dialysate precursor composition is minimal. All of the guidance provided by the specification is directed towards specific type of iron (e.g. ferric lactate).

Working Examples: All of the working examples provided by the specification are directed toward inclusion of the specific iron form rather than any iron.

State of the Art: While the state of the art is relatively high with regard to dialysate precursor composition with specific type of iron the state of the art with regard a dialysate precursor composition with any type of iron is underdeveloped. In particular, there do not appear to be any examples or teachings in the prior art wherein any type of iron was included in a dialysate precursor composition. The state of the art, Ash (WO 98/06482A1) of record, teach that iron dextran causes severe allergic reactions, fever and rashes during injection and that only about half of iron in the iron dextran is bio-available after intravenous injection for red

cell production; ferric gluconate is another macromolecular iron complex requiring a great deal of time and skill for administration. (page 4, lines 1-20). Therefore, it is highly speculative that any type of iron would work as a precursor dialysate to serve as a dialysate composition.

Predictability of the Art: The lack of significant guidance from the specification or prior art with regard inclusion of any types the claimed inclusion of iron makes practicing the claimed invention unpredictable in terms of the utilization of any type of iron.

The amount of Experimentation Necessary: In order to practice claimed invention, one of skilled in the art would have to first envision a combination of appropriate pharmaceutical carrier, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system for one of the claimed iron and test the combination in the model system to determine whether or not the combination is effective for a dialysate composition. If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art regard to inclusion of any type of iron, one of skill in the art would have to then either envision a modification of the first combination of pharmaceutical compound, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system, or envision an entirely new combination of the above, and test the system again. If again unsuccessful, which is likely given the lack of significant guidance form the specification of prior art regarding utilization of any iron, the entire, unpredictable process would have to be

repeated until successful. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention of inclusion of iron to formulate a precursory dialysate precursor.

Therefore, a dialysate precursor composition comprising citrate at a concentration raging from about 20 to about 900mEq/L; a buffering anion selected from acetate and/or lactate; water; chloride at a concentration ranging from about 1,000 to about 7,000 mEq/L; at least one physiologically-acceptable cation; and a therapeutically effective amount of **iron** is not considered to be enabled by the instant specification.

None of the claims are allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER M. KIM whose telephone number is (571)272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer Kim/
Primary Examiner, Art Unit 1617

Jmk
December 22, 2008